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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAVID PERRY Plaintiff, vs. ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA, LP, KBI SUB INC. Defendants.	)	COMPLAINT FOR DAMAGES JURY DEMAND

COMPLAINT

COMES NOW the Plaintiff, by and through his undersigned attorney, and for his Complaint against AstraZeneca Pharmaceuticals LP and AstraZeneca, LP, (hereinafter "AstraZeneca" or "Defendants") and alleges as follows:

1. This action is brought by Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, Seroquel, which was manufactured, marketed, distributed and/or sold by AstraZeneca to the general public.

JURISDICTION AND VENUE

2. The Court has jurisdiction over this lawsuit under 28 U.S.C. § 1332 as the amount

in controversy exceeds $75,000, excluding interest and costs and there is diversity of the parties. Venue is proper in this district based upon Defendants' commercial activities and Defendant KBI Sub Inc.'s residence.

3. Defendants placed the dangerous and defective pharmaceutical atypical antipsychotic drug Seroquel into the stream of interstate and worldwide commerce, including the State of New Jersey.

4. As a direct and proximate result of Defendants placing Seroquel into the stream of commerce, Plaintiff has suffered and continues to suffer injuries including, but not limited to physical, mental and economic loss, pain and suffering, and she will continue to experience such injuries indefinitely.

5. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited and conducted business in the State of New Jersey and derived substantial revenue from such business.

6. At all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States and the State of New Jersey.

7. This action includes claims for injuries to Plaintiff caused by his ingestion of Seroquel and therefore should be, and plaintiff consents to, transfer to **Multidistrict Litigation No. 1769 In Re: Seroquel Products Liability Litigation**, United States District Court, Middle District of Florida, Orlando Division, the Honorable Anne C. Conway.

PARTIES

8. Plaintiff, David Perry, is a resident of Fort Worth, Texas. Plaintiff was prescribed, purchased and ingested Seroquel. After using Seroquel, Plaintiff was diagnosed with Diabetes

Mellitus.

9. AstraZeneca Pharmaceuticals LP, is a Delaware limited partnership doing business in the State of Delaware, and the United States. AstraZeneca Pharmaceuticals LP, is the United States Subsidiary of AstraZeneca PLC, and was created as a result of the union of Zeneca Pharmaceuticals and Astra Pharmaceuticals LP in the United States after the 1999 merger. AstraZeneca Pharmaceuticals LP's principal place of business is in Delaware, 1800 Concord Pike, P.O. Box 15347, Wilmington, Delaware 19850. Upon information and belief AstraZeneca Pharmaceuticals LP's general and limited partners are: AstraZeneca AB, a Swedish corporation with its principal place of business in Sweden; Zeneca Inc., a Delaware corporation with its principal place of business in Delaware; Astra USA Inc., a New York corporation with it's principal place of business in Delaware; and Astra US Holdings Corporation, A Delaware corporation with it's principal place of business in Delaware. Therefore, AstraZeneca Pharmaceuticals LP is a citizen of Delaware, New York and Sweden.

10. Defendant, AstraZeneca LP, is a Delaware limited partnership doing business in the State of Delaware and the United States. AstraZeneca LP's principal place of business is in Delaware. Upon information and belief AstraZenecca LP's general partner is AstraZeneca Pharmaceuticals LP, which as stated above is a citizen of Delaware, New York, and Sweden. AstraZeneca LP's sole limited partner, KBI Sub Inc., is incorporated in the State of Delaware and its principal place of business is in New Jersey. Therefore, AstraZeneca LP is a citizen of Delaware, New York, New Jersey and Sweden.

11. Defendant KBI Sub, Inc. is incorporated in the States of Delaware and its principal place of business is in New Jersey. Upon information and belief, Defendant KBI Sub, Inc.'s Registered Agent for the Service of Process is the Corporation Trust Company located at

Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Upon information and belief, Defendant KBI Sub, Inc. is doing business in the State of New Jersey. Defendant KBI Sub Inc. is AstraZeneca LP's sole limited partner. Therefore, Defendant KBI Sub Inc. is a citizen of the State of Delaware and New Jersey.

12. AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and KBI Sub Inc., shall be collectively referred to as "AstraZeneca" or "Defendants". At all times relevant herein, the Defendants' were in the business of designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Seroquel, for the use by the mainstream public, including Plaintiff Scott Zwilling.

FACTUAL BACKGROUND

13. This is an action against the AstraZeneca Defendants on behalf of the Plaintiff who was prescribed the prescription drug Seroquel, which is an "anti-psychotic" medication belonging to a class of drugs referred to as "atypical anti-psychotics".

14. Plaintiff ingested the prescribed dosage of said drug in accordance with the prescription written for the Plaintiff.

15. Seroquel causes serious and sometimes fatal injuries including but not limited to, ketoacidosis, pancreatitis, and diabetes mellitus, and other serious health problems associated with the onset of diabetes including heart disease, blindness, coma, seizures and death.

16. At all times relevant herein, the AstraZeneca Defendants, either directly or through their agents, servants, and employees, designed, manufactured, marketed, advertised, distributed, and sold Seroquel for the treatment of schizophrenia, bipolar disorder, and other "off-label" uses.

17. Those persons who were prescribed and ingested Seroquel, including Plaintiff, have suffered severe and permanent personal injuries, including diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, diabetic coma, and death, as well as other severe and permanent injuries.

History of Seroquel

18. In September 1997, the Food and Drug Administration ("FDA") approved the newest "atypical anti-psychotic," Seroquel, for use in the United States. At that time, Seroquel was approved for use in dosages of 25 mg, 100 mg and 200mg tablets.

19. Seroquel is now available in 25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg dosages.

20. The prescription drug Seroquel is an "anti-psychotic" medication, belonging to a class of drugs referred to as "atypical anti-psychotics". Other atypical anti-psychotics include Zyprexa (Eli Lilly), Risperdal (Johnson & Johnson) and Abilify (Bristol-Myers Squibb), which have been in use in the United States since the early to mid 1990's.

21. Seroquel is a medication commonly prescribed to patients to aid in the treatment of mental disorders including schizophrenia. The pharmacologic action of Seroquel is thought to be dependent on its ability to block or moderate the level of dopamine, a chemical found in the brain that in excessive amounts is believed to cause abnormal thinking and hallucinations. It appears to work primarily by blocking neurotransmitter sites of serotonin and dopamine, as well as histamine receptors.

22. Seroquel was widely advertised, marketed and represented by the AstraZeneca Defendants, in its label, package insert, *Physicians Desk Reference* entry and otherwise, as a safe and effective atypical anti-psychotic.

23. Seroquel was marketed heavily by the AstraZeneca Defendants as a safe and effective treatment for schizophrenia and the AstraZeneca Defendants' promised fewer side effects than other similar treatments including the other atypical anti-psychotics on the market.

24. The AstraZeneca Defendants, through their marketing departments, sales managers, and field sales force and other agents, servants and employees promoted the drug for uses beyond its approved indications, offering incentives to doctors to increase prescriptions. Through these marketing efforts, the AstraZeneca Defendants were able to capture a larger market share in the anti-psychotic market.

25. These marketing efforts were designed and implemented to create the impression in physicians', patients' and plaintiff's minds that Seroquel was safe and effective and that it carried less risk of side effects and adverse reactions than other available treatments.

26. The marketing and promotion efforts of the AstraZeneca Defendants, their agents, servants and/or employees served to overstate the benefits of Seroquel and minimize and downplay the risks associated with the drug.

27. On May 6, 1999, the AstraZeneca Defendants were told by the FDA that materials they continued to distribute, despite a warning letter dated November 24, 1998, were "determined to be false, lacking in fair balance, or otherwise misleading, and in violation of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder."

28. The FDA had specific objections to numerous promotional materials that they directed be "[I]mmediately discontinued...". These objections involved the AstraZeneca Defendants use of promotional materials and included the following:

a. Materials that state or imply that Seroquel is effective in a broader range of mental conditions, including bipolar disorder and schizoaffective disorder, are misleading (e.g., brochures #SQ1035, #SQ1112). Seroquel is

indicated for the manifestations of psychotic disorders as determined by clinical trials in schizophrenic inpatients. Application to broader or additional mental disorders would require substantiation from adequate and well-controlled studies designed to examine the specific mental conditions.

b. The mechanism of action of Seroquel, as well as other antipsychotic drugs, is unknown. Therefore, materials that discuss how Seroquel "works" without stressing the theoretical nature of this information, are misleading (e.g., brochures #SQ1059, #PR1048).

c. Materials in which the prominence and readability of the risk information fails to be reasonably comparable to the information regarding the effectiveness of Seroquel lack fair balance (e.g., journal ad #SQ1089, brochure #SQ1139). In addition, materials that fail to disclose the important warnings and precautions (i.e., neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension, risk of cataract development, and seizures) are lacking fair balance because these are considered to be priority safety consideration (e.g, journal #SQ1088).

29. The AstraZeneca Defendants made affirmative assertions of material fact including but not limited to Seroquel was safe if used as directed, no specific laboratory tests were recommended and Seroquel was safer than other alternative medications.

30. The AstraZeneca Defendants knew these assertions to be false or recklessly failed to ascertain their truth or falsity.

31. The AstraZeneca Defendants also fraudulently concealed important safety information from physicians, the FDA, the public and Plaintiff, including but not limited to the AstraZeneca Defendants' awareness of numerous reports of diabetes associated with the use of Seroquel, beyond the background rate, and beyond the rate for other anti-psychotic agents. The AstraZeneca Defendants as manufacturers of ethical drugs had a duty to disclose said information.

32. The AstraZeneca Defendants were aware that the drug caused diabetes mellitus, pancreatitis and ketoacidosis, but the AstraZeneca Defendants concealed such information and made misrepresentations that the drug was safe.

33. The anti-psychotic drug market is one of the largest drug markets worldwide.

34. The AstraZeneca Defendants viewed Seroquel as a blockbuster product with significant projected growth potential. In 2002 alone, Seroquel reached over $1.1 Billion in sales.

35. Upon information and belief, Seroquel is one of the AstraZeneca Defendants= top-selling drugs.

36. Since the AstraZeneca Defendants introduced Seroquel in 1997, over 24.6 million prescriptions have been made and it has been prescribed to more than 13 million people worldwide.

37. In 2003, approximately seven million prescriptions for Seroquel were dispensed, resulting in more than $2 Billion in sales.

38. In 2005, Seroquel reached approximately $2.7 Billion in annual sales and controlled approximately 31% of the market share for atypical anti-psychotics.

39. Worldwide sales for Seroquel in the first quarter of 2006 compared with sales a year ago in the same period were $807 million, up 27 percent.

Adverse Effects Related To Seroquel Use

40. In an extensive independent study of over 8,000 New York mental health patients, published in September of 2004, it was found that the risk of diabetes was over 300% higher in patients who took Seroquel.

41. The use of Seroquel is now known by the public, the FDA and physicians to cause serious and sometimes fatal injuries including, but not limited to, ketoacidosis, pancreatitis, and diabetic mellitus, and other serious health problems associated with diabetes including heart disease, blindness, coma, seizures and death.

42. In August 2003, the AstraZeneca Defendants became further aware of the link between Seroquel and diabetes. These new reports, described an increased incidence of diabetes in patients receiving Seroquel, than in patients receiving older anti-psychotics, or even other atypicals, including Zyprexa, Clozaril and Risperdal.

43. The reported risk associated with Seroquel and the onset of diabetes is nearly 3.34 times higher than older drugs used to treat schizophrenia, such as Haldol. According to these reports, compared to other drugs in its class, Zyprexa, (Eli Lilly & Co.) - 1.27 times more likely, and Risperdal (Johnson & Johnson) - 1.49 times more likely, Seroquel has a much greater increased association with the onset of diabetes mellitus than any other anti-psychotic on the market.

44. Consumers, including Plaintiff, who have used Seroquel, have available several alternative atypical anti-psychotic medications.

45. In fact, in December 2000, the AstraZeneca Defendants knew that there was no clear evidence that Seroquel was more effective or better tolerated than conventional anti-psychotics including Haldol and Thorazine.

46. It should be noted that there is a significant difference among the costs of Haldol and Seroquel per month: $35 versus $414, respectively.

Seroquel Causes Diabetes and Other Serious Injuries

47. Shortly after the AstraZeneca Defendants began selling Seroquel, the AstraZeneca Defendants began to receive reports of consumers who were using Seroquel suffering from hyperglycemia, acute weight gain, exacerbation of diabetes mellitus (hereinafter Adiabetes@), development of diabetes, pancreatitis, and other severe diseases and conditions. The AstraZeneca Defendants knew, or should have been aware of these reports.

48. By July 2001, the AstraZeneca Defendants had received at least 46 reports of patients taking Seroquel and developing hyperglycemia or diabetes mellitus, of which there were 21 cases of ketoacidosis or acidosis and 11 deaths. By December 31, 2003, the AstraZeneca Defendants had received reports of at least 23 additional cases, bringing the total to 69. Most of these patients developed the above conditions within six months of their use of Seroquel.

49. The AstraZeneca Defendants were or should have been aware of studies and articles in 1998 and 1999 confirming a link between drugs like Seroquel and new onset diabetes and permanent hyperglycemia related adverse events. *Wirshing. DA, Novel Antipsychotics and New Onset Diabetes.* Biol. Psychiatry, 1998:15, 44:778-83; *Allison, DB, Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis.* Am. J. Psychiatry, 1999:156:1686-96.

50. Studies conducted in the United States and Europe have established that numerous patients treated with Seroquel experienced a significantly higher incidence of severe and permanent diseases and conditions, including dangerous rises in blood glucose levels.

Defendants' Failure to Warn of the Dangers of Seroquel

51. At the time of the prescription of Seroquel to the Plaintiff, the AstraZeneca Defendants had not adequately warned Plaintiff or his/her physicians, and/or did not adequately

and effectively communicate all warnings about the risk of diabetes, hyperglycemia, diabetic ketoacidosis, or other serious injuries caused by Seroquel.

52. The product warnings for Seroquel in effect during the relevant time period were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as consumer patients of the actual risks presented by the use of this drug.

53. In fact, the product information section for Seroquel in the *Physicians Desk Reference* for the years 1999, 2000, 2001, 2002, 2003 and 2004, contains no statement in the WARNINGS section to alert anyone of the risks of diabetes, ketoacidosis or pancreatitis associated with the use of Seroquel.

54. However, in Japan, the AstraZeneca Defendants warned of the risks of diabetes since 2002.

55. The Japanese "label" for Seroquel provides, and has provided since 2002, a detailed warning regarding the risks of diabetes associated with Seroquel, and specifically informs physicians regarding the necessity of monitoring patients on Seroquel. At the time Plaintiff ingested Seroquel, the AstraZeneca Defendants had not adopted this label for the distribution of Seroquel in the United States.

56. The label the AstraZeneca Defendants issued in Japan, but not in the United States, warns specifically of the diabetes risk, prominently in the beginning of the package label stating:

a. Quetiapine is contraindicated for use in patients with diabetes or a history of diabetes;

b. Quetiapine should be used with caution in patients with risk factors for diabetes, including hyperglycemia, obesity or a family history of diabetes;

c. Patients receiving quetiapine should be carefully monitored for symptoms of hyperglycemia and the drug should be discontinued if such symptoms occur. The symptoms of severe hyperglycemia include weakness, excessive eating, excessive thirst, and excessive urination; and,

d. Physicians should educate patients and their family members about the risk of serious hyperglycemia associated with quetiapine and how to identify the symptoms of hyperglycemia.

57. On September 11, 2003, the FDA informed the AstraZeneca Defendants that they must make labeling changes to Seroquel, due to an increasing prevalence of diabetes-related illnesses associated with this drug. The following information appeared in the WARNINGS section for Seroquel in the 2005 *Physicians Desk Reference*:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including Seroquel. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

58. Recently, researchers at the National Institute of Mental Health published a report on atypical anti-psychotics, including Seroquel, which found that the majority of patients in each group discontinued their assigned treatment owing to inefficacy or intolerable side effects or for other reasons and that the atypicals, including Seroquel, were no more effective than the older, cheaper, and still available conventional antipsychotic perphenazine. This report echoes the conclusions reported in the *British Medical Journal* in 2000.

59. The AstraZeneca Defendants misrepresented and failed to appropriately warn consumers, including Plaintiff, and the medical and psychiatric communities of the dangerous risk of developing diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences caused by Seroquel, and consequently placed their profits above the safety of its customers.

60. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require constant and continuous medical care and treatment.

Plaintiff's Use of Seroquel

61. Plaintiff was prescribed and began taking Seroquel as prescribed by his prescriber.

62. Plaintiff used Seroquel as prescribed and in a foreseeable manner.

63. As a direct and proximate result of using Seroquel, Plaintiff was seriously injured and developed the permanent, life threatening condition of diabetes.

64. Plaintiff, as a direct and proximate result of ingesting Seroquel, has suffered severe pain and has sustained permanent injuries and emotional distress.

65. Had Plaintiff known of the full extent of the risks and dangers associated with Seroquel, Plaintiff would not have taken Seroquel.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

66. The running of any statute of limitation has been tolled by reason of the AstraZeneca Defendants' fraudulent conduct. The AstraZeneca Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with taking Seroquel.

67. As a result of the AstraZeneca Defendants actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the AstraZeneca Defendants= acts and omissions.

68. Furthermore, the AstraZeneca Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the truth, quality and nature of Seroquel. The AstraZeneca Defendants were under a duty to disclose the true character, quality and nature of Seroquel because this was a non-public information over which the AstraZeneca Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. In addition, the AstraZeneca Defendants are estopped from relying on any statue of limitation because of their intentional concealment of these facts.

69. The Plaintiff had no knowledge that the AstraZeneca Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the AstraZeneca Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The AstraZeneca Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably

known risks. Plaintiff and his/her medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on the AstraZeneca Defendants' representations.

COUNT I
NEGLIGENCE & RECKLESSNESS

70. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

71. The AstraZeneca Defendants were in the business of testing, designing, manufacturing, packaging, promoting, distributing, performing quality assurance evaluations and/or selling Seroquel.

72. The AstraZeneca Defendants owed a duty of reasonable care to Plaintiff to license, test, design, manufacture, package, properly and adequately warn, promote, distribute, perform quality assurance evaluations, and/or sell Seroquel in a safe condition.

73. The AstraZeneca Defendants had a duty not to introduce a pharmaceutical drug, such as Seroquel, into the stream of commerce that caused users of said drug, including Plaintiff to suffer from unreasonable, dangerous and adverse side effects.

74. The AstraZeneca Defendants breached their duty in that they and/or their agents servants or employees failed to exercise reasonable care and were negligent and/or were reckless in the licensing, testing, quality assurance, design, manufacture, packaging, warning, advertising, promotion, distribution and sale of the product.

75. The AstraZeneca Defendants' conduct was wanton, reckless and malicious so as to permit the recovery of punitive damages.

76. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

77. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
FRAUD

78. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

79. As set forth under the facts herein, and pending discovery, the AstraZeneca Defendants' representatives through national advertising, promotional campaigns, standardized package inserts, related materials, purchased or subsidized so-called expert opinions both orally and in print and in correspondence to healthcare professionals, and in submissions and reports to the FDA, and product information regarding the characteristics of and the quality of Seroquel,

were false, misleading, materially incorrect in fact, and were made knowingly, intentionally, and/or willfully to deceive without regard to the safety and use of the product and were acted on in reasonable reliance by Plaintiff's prescribing physicians and medical professionals and Plaintiff, to Plaintiff's substantial detriment and injury.

80. The AstraZeneca Defendants distributed false and misleading materials to physicians, Plaintiff's prescribers and Plaintiff that the FDA "determined to be false, lacking in fair balance, or otherwise misleading, and in violation of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder."

81. The FDA directed that the AstraZeneca Defendants discontinued the use of various promotional materials that were distributed to physicians, Plaintiff's prescribers and Plaintiff and stated as follows:

a. Materials that state or imply that Seroquel is effective in a broader range of mental conditions, including bipolar disorder and schizoaffective disorder, are misleading (e.g., brochures #SQ1035, #SQ1112). Seroquel is indicated for the manifestations of psychotic disorders as determined by clinical trials in schizophrenic inpatients. Application to broader or additional mental disorders would require substantiation from adequate and well-controlled studies designed to examine the specific mental conditions.

b. The mechanism of action of Seroquel, as well as other antipsychotic drugs, is unknown. Therefore, materials that discuss how Seroquel "works" without stressing the theoretical nature of this information, are misleading (e.g., brochures #SQ1059, #PR1048).

c. Materials in which the prominence and readability of the risk information fails to be reasonably comparable to the information regarding the effectiveness of Seroquel lack fair balance (e.g., journal ad #SQ1089, brochure #SQ1139). In addition, materials that fail to disclose the important warnings and precautions (i.e., neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension, risk of cataract development, and seizures) are lacking fair balance because these are considered to be priority safety consideration (e.g, journal #SQ1088).

82. Material information concerning the development of a serious injury related to the use of Seroquel was fraudulently concealed by the AstraZeneca Defendants from Plaintiff's treating physicians and Plaintiff. The FDA had received reports of 11 Seroquel related deaths and numerous diabetes related injuries. The AstraZeneca Defendants knew or reasonably should have known of this information and this information was not disclosed to Plaintiff's physicians or to Plaintiff.

83. As part of the warning label in Japan, the AstraZeneca Defendants were required to disclosed that individuals with diabetes or a family history of diabetes should not take Seroquel. This important and material information was not communicated to Plaintiff's physicians or to Plaintiff in the United States.

84. The AstraZeneca Defendants intended that the Plaintiff's physicians and patients, including Plaintiff would rely upon such misrepresentations.

85. The AstraZeneca Defendants' representations as set forth above regarding the quality and characteristics of Seroquel were willful and/or reckless misrepresentations of material fact made with the intent to induce Plaintiff and Plaintiff did, without knowledge of their falsity, directly or indirectly, justifiably act upon those willful misrepresentations to Plaintiff's injury.

86. Plaintiff relied to their detriment on these material misrepresentations and suffered serious injuries including but not limited to diabetes mellitus, ketoacidosis and pancreatitis.

87. As a result of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

88. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
FRAUDULENT CONCEALMENT

89. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

90. As set forth under the facts herein, and pending discovery, the AstraZeneca Defendants fraudulently concealed from the Plaintiff's physicians and Plaintiff that Seroquel was dangerous and not as effective for its purpose as represented, and imposed greater risks than disclosed.

91. The AstraZeneca Defendants as the manufacturer of ethical drugs were under a duty to timely disclose adequate warnings and information to the medical profession, Plaintiff's prescribers and Plaintiff under laws requiring them not to engage in false and deceptive trade

practices, and because the AstraZeneca Defendants were experts in the field, they are under a continuous duty to keep abreast of scientific developments touching on Seroquel and to know the true state of the facts about the dangerous and defective nature of Seroquel.

92. The AstraZeneca Defendants had actual knowledge gained from research and adverse event reports and constructive knowledge from scientific literature and other means of communication to know of the true risks of Plaintiff's use of Seroquel. This medical information was fraudulently concealed from Plaintiff's physicians and Plaintiff.

93. Material information concerning the development of a serious injury related to the use of Seroquel was fraudulently concealed from Plaintiff's treating physicians and Plaintiff. The FDA had received reports of 11 Seroquel related deaths and numerous diabetes related injuries. The AstraZeneca Defendants knew or reasonably should have known of this information and this information was not disclosed to Plaintiff's physicians or to Plaintiff.

94. Significantly, the AstraZeneca Defendants were required to disclose in Japan specific information that individuals with diabetes or a family history of diabetes should not take Seroquel. This important and significant information was not communicated to Plaintiff's physicians or to Plaintiff in the United States.

95. The AstraZeneca Defendants also concealed information that in Japan they had warned, that if a patient developed symptoms of hyperglycemia, then patients should be carefully monitored and Seroquel should be discontinued. This material information was not disclosed and was fraudulently concealed from Plaintiff's physicians and Plaintiff in the United States.

96. These intentional representations suppressed and/or concealed material facts, including but not limited to:

a. suppressing and/or mischaracterizing the known risks to health and effectiveness;

b. failing to timely and fully disclose the results of tests and studies on the risks to health and effectiveness;

c. failing to disseminate adequate warnings which would disclose the nature and extent of the side effects of the product, the risks to health and effectiveness;

d. failing to disclose that adequate and/or standard and/or generally accepted standards for pre-clinical testing had not been done;

e. failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done;

f. failing to disclose that alternative products and methods available posed less risks than Seroquel and were at least effective;

g. failing to conduct adequate tests and studies on the product prior to marketing and making representations as set forth in this complaint;

h. failing to reveal the full nature and extent of the known risks and hazzards associated with Seroquel; and

i. as otherwise described in this complaint to be discovered during this litigation and to be proven at trial.

97. Plaintiff had no knowledge of the dangerous risks associated with the use of Seroquel and relied on the AstraZeneca Defendants fraudulent representations and suffered injury as a result thereof.

98. Plaintiff could not have taken any action to reasonably discover that the AstraZeneca Defendants representations were false and fraudulent.

99. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

100. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
FAILURE TO ADEQUATELY WARN

101. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

102. The AstraZeneca Defendants, as a manufacturer of pharmaceuticals, had a duty to warn of adverse drug reactions, which they know or have reason to know, are inherent in the use of its pharmaceutical products.

103. The AstraZeneca Defendants failed to adequately warn Plaintiff, Plaintiff's physicians and the general public of the risks of Seroquel being used by Plaintiff.

104. The AstraZeneca Defendants failed to adequately warn of dangers inherent with the use of Seroquel and the AstraZeneca Defendants misrepresentations and inadequate disclosures to the Plaintiff's physicians, Plaintiff, and the general public, made the product unreasonably dangerous for normal use.

105. The AstraZeneca Defendants are strictly liable in tort to the Plaintiff upon the grounds that:

a. Seroquel was unsafe, defective and unreasonably dangerous for its intended and/or foreseeable uses, by reason of inadequately warning and/or inadequately communicating warnings.

b. In distributing, promoting and selling Seroquel not accompanied by adequate warnings of the dangers that were known or should have been known; by failing to provide adequate warnings regarding all known or reasonably knowable potential side effects associated with the use of Seroquel, and the comparative nature, extent, severity, incidence and duration of such adverse effects; failing to provide adequate warnings regarding the signs, symptoms, incidence, scope or severity of the side effects, and/or identify appropriate testing, monitoring and/or remedial action; failing to provide adequate warnings in a timely manner and information necessary for their purposes, thus placing the Plaintiff and consuming public at risk;

c. The AstraZeneca Defendants were aware that Seroquel would be used without inspection and study for the defects inherent in Seroquel as alleged, and that given the resources of the Plaintiff and

his/her physicians, any reasonably anticipated inspection would have failed to detect the defects;

d. The AstraZeneca Defendants expected and knew that Seroquel would reach the consuming public and Plaintiff. Seroquel was, in fact, received by Plaintiff without change in the condition in which the drug and its labeling was first manufactured and sold.

e. Plaintiff was a foreseeable users of the product in its intended manner and suffered serious harm because of said use.

106. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the AstraZeneca Defendants knew or should have known of the risks of injury from Seroquel use, they failed to provide adequate warnings to consumers of the product, including Plaintiff, and continued to aggressively promote Seroquel.

107. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

108. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
STRICT LIABILITY-DEFECTIVE DESIGN

109. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

110. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was placed into the stream of commerce in a defective and unreasonably unsafe condition in that the foreseeable risks of its use exceeded the benefits associated with the design or formulation.

111. The AstraZeneca Defendants knew or should have known at the time of manufacture that Seroquel was defective in design or formulation and that Sequel created a risk of harm to consumers such as Plaintiff when used in the way it was intended to be used and in a manner which was reasonably foreseeable by the AstraZeneca Defendants.

112. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was placed into the stream of commerce when they knew or should have known of the defective design or formulation and a reasonable person would have concluded that the utility of Seroquel did not outweigh the risk inherent in marketing Seroquel designed in that manner.

113. As set forth in this complaint and otherwise, the AstraZeneca Defendants knew of Seroquel's defective nature at the time of its manufacture, but continued to design, manufacture, market, promote, represent to the consuming public, prescribers, and

Plaintiff that Seroquel was safe for the sole purpose of maximizing sales and profits at the expense of the public health and safety in conscious disregard of foreseeable harm caused by Seroquel.

114. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

115. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY

116. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

117. The AstraZeneca Defendants expressly warranted that Seroquel was safe for its intended use and as otherwise described in this complaint. Seroquel did not conform to these express representations, including, but not limited to, the representation

that it was well accepted in patient studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects and as otherwise set forth in this complaint and/or AstraZeneca Defendants' materials.

118. The express warranties represented by the AstraZeneca Defendants were a part of the basis for Plaintiff's use of Seroquel.

119. At the time of the making of the express warranties, the AstraZeneca Defendants had knowledge of the purpose for which the aforestated product was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

120. Seroquel does not conform to these express representations because Seroquel is not safe or effective and may produce serious side effects, including among other things, diabetes, pancreatitis, ketoacidosis and death.

121. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

122. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

123. The AstraZeneca Defendants impliedly warranted that it would sell and deliver Seroquel in a condition that was fit for the particular purposes for which it was intended.

124. The AstraZeneca Defendants knew that Plaintiff intended to use the Seroquel for the particular purpose of medication and that as such, that the medication needed to be safe for use by Plaintiff.

125. Plaintiff relied upon the AstraZeneca Defendants' skill and/or judgment in their ability to furnish suitable Seroquel that was safe for its intended use.

126. The Seroquel was not safe for its intended use in that it was defective and caused serious side effects and the AstraZeneca Defendants therefore breached its implied warranty of fitness for a particular purpose.

127. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

128. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and

physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

129. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

130. At all times material hereto, the AstraZeneca Defendants marketed, sold and distributed Seroquel and knew and promoted the use for which the aforesaid drug was being used by Plaintiff and impliedly warranted to Plaintiff that Seroquel was of merchantable quality and fit for the ordinary purpose for which it was intended.

131. Plaintiff reasonably relied on the skill, expertise and judgment of the AstraZeneca Defendants and its representations as to the fact that Seroquel was of merchantable quality.

132. The Seroquel manufactured and supplied by the AstraZeneca Defendants was not of merchantable quality, as warranted by the AstraZeneca Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

133. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

134. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS

135. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

136. The AstraZeneca Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of their drugs, including but not limited to the risks of diabetes mellitus and other injuries. Further, the AstraZeneca Defendants purposely downplayed and understated the serious nature of the risks associated with use of their drugs in order to increase the sales of those drugs.

137. The AstraZeneca Defendants knew or should have known (and would have known had appropriate testing been done) that use of their drugs caused serious and potentially life-threatening side effects.

138. The AstraZeneca Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of their drugs and did so because the prospect of significant future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including the Plaintiff.

139. Many safer and less expensive anti-psychotics were available to patients being treated with the AstraZeneca Defendants' drugs.

140. The AstraZeneca Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from their drugs, and succeeded in persuading large segments of the relevant consumer market to request their drugs and large segments of the medical community to prescribe their drugs, despite both the lack of efficacy and the presence of significant dangers, as set forth herein.

141. The AstraZeneca Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that their drugs were injurious or fatal.

142. The AstraZeneca Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of their drugs, including but not limited to the risks of death, disease and other health problems associated with the use of their drugs. The AstraZeneca Defendants have purposely downplayed and/or understated the serious nature of the risks associated with the use of their drugs and have implicitly encouraged the use of these drugs despite knowledge of the dangerous side effects that their drugs presents to the patient population.

143. The AstraZeneca Defendants purposefully and knowingly promoted their drugs for "off label" uses beyond the scope of the FDA approved uses and beyond those uses supported by medical science.

144. The AstraZeneca Defendants unlawfully provided financial incentives to physicians and others to prescribe and approve "off label" uses.

145. The AstraZeneca Defendants knew or should have known, and would have known had appropriate testing been done, that the use of their drugs caused the serious and potentially life threatening side effects.

146. The AstraZeneca Defendants' actions as set forth herein constitute knowing omission, suppression or concealment of material facts, made with the intent that others would rely upon such concealment, suppression or omission, in connection with the marketing, sale and use of their drugs.

147. In fact, the Plaintiff directly and/or through prescribing physicians was induced by the AstraZeneca Defendants' omissions and suppression and concealment of facts to use AstraZeneca Defendants' drugs.

148. As a direct and proximate result of the Plaintiff's ingestion of AstraZeneca Defendants' drugs caused by the aforesaid acts and failures to act by the AstraZeneca Defendants, Plaintiff suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

149. The AstraZeneca Defendants' conduct is outrageous because of reckless indifference to the health and safety of Plaintiff and to the public so as to justify an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against the AstraZeneca Defendants for damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past and future lost wages, and punitive damages, together with interest from the date of injury and costs.

COUNT X
UNJUST ENRICHMENT

150. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.

151. Defendant has been unjustly enriched in the amount of the profits they have earned as a result of Defendant's conduct as alleged herein.

152. Defendant has been unjustly enriched at the expense of and to the detriment of the Plaintiff.

153. As a direct and proximate cause of Defendants conduct, the Plaintiff demands judgment in her favor and against AstraZeneca in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

WHEREFORE, Plaintiff demands judgment against the AstraZeneca Defendants for damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past and future lost wages, and punitive damages, together with interest from the date of injury and costs.

Dated: June 16, 2008

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

THE MILLER FIRM, LLC
Attorneys for Plaintiff

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

The undersigned attorney for Plaintiff certifies that the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration or administrative proceeding.

I certify that the foregoing statement made by me is true to the best of my knowledge, information and belief. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

Michele A. DiMartino, Esquire

Dated: June 16, 2008

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A., 56:8-20, Plaintiff is mailing a copy of this Complaint and Jury Demand to the Office of Attorney General, Cn-006, Trenton, New Jersey, within (10) days of the filing of this Complaint and Jury Demand.

Michele A. DiMartino, Esquire

Dated: June 16, 2008

MICHAEL J. MILLER, ESQ.*
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Attorneys for Plaintiffs
* Admission Pro Hac Vice To Be Filed